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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,306	11/07/2000	Li-Wei Hsu	205032000400	1255

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/708,306	HSU ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2004 and 25 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-20 and 25-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-20 and 25-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/16/04 has been entered.

Amendment Entry

2. Applicant's response filed October 25, 2004 is acknowledged and has been entered. Claims 14, 15, 25, and 31 have been amended. Claims 32-42 have been added. Accordingly, claims 14-20 and 25-42 are pending and are under examination.

Rejections Withdrawn

3. All rejections not reiterated herein have been withdrawn in light Applicant's amendment and arguments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 14-17, 19, 20, 25-27, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US Patent 6,087,103) in view of Baek et al. (Agricultural Chemistry and Biotechnology, April 1998 (Abstract)).

Burmer discloses screening methods and kit that can readily be used to simultaneously identify multiple proteins or compounds that can interact with multiple tagged array of ligands and which can be used to identify new pharmacologically useful agents (see Abstract). The methods use an array of pooled, tagged ligands which are coated (arrayed) spatially in a matrix such as plastic plate (microtiter dish) and wherein each ligand is bound to a unique tag that has a known address (see column 1, lines 47-60, column 3, lines 39-46, and column 11, lines 16-64). The ligand may be, e.g. small organic molecules, a peptide or a polypeptide (see column 4, lines 23-29). The ligand

libraries of small organic molecules, peptides or polypeptides can be obtained by combinatorial methods, or can be obtained as natural products such as microbial fermentation cultures, or as ligands encoded by nucleic acid libraries which are extracted and isolated from plant or animal tissue. The polypeptides coated on the matrix of the plastic plate are contacted with labeled target proteins, incubated, washed with a buffer to remove unbound components, and then detected for binding of the labeled target to any one of the peptide arrays (see column 8, lines 12-65, column 15, lines 8-24, column 3, lines 62-67, and column 14, lines 19-24). Useful labels for the method and kit include biotin (see column 2, lines 14-17 and column 5, lines 11-23).

Burmer differs from the instant invention in failing to disclose extracting and fractionating polypeptides from crude plant extract using chromatography. Burmer also fails to disclose that the plant extract is from an herb, which is Carthamus tinctorius.

Baek et al. teach extracting and fractionating polypeptides from crude plant extract, i.e. Carthamus tinctorius. Two biologically active flavonoid compounds have been isolated by repeat silica gel column chromatographies.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the fractions of polypeptides extracted from Carthamus tinctorius as taught by Baek into the plastic plate or microtiter dish used in the method and kit of Burmer, because Burmer specifically suggested obtaining ligands from any plant or animal tissue for use in simultaneously screening for compounds with biological activity and pharmacological utility, i.e. antithrombotic activity, and Baek

specifically extracted and fractionated polypeptides from C. tinctorius using chromatographic methods to obtain protein or polypeptide fractions for subsequent testing.

5. Claims 18, 28, and 31-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US Patent 6,087,103) in view of Baek et al. (Agricultural Chemistry and Biotechnology, April 1998 (Abstract)) as applied to claims 14-17, 19, 20, 25-27, 29, and 30 above, and in further view of Kutsuna et al. (Journal of the Pharmaceutical Society of Japan, November, 1988) (Abstract)).

Burmer and Baek et al. have been discussed supra. Burmer and Baek et al. differ from the instant invention in failing to teach that the protein target is a glycoprotein or a platelet membrane receptor protein.

Kutsuna et al. isolate, identify, and determine a biologically active compound from safflower Carthamus tinctorius. The compound is a platelet aggregation inhibitor which exhibits in vivo anti-thrombotic activity, and which inhibits glycoprotein (GPIIbIIIa) binding to serum proteins. The compound is induced by adenosine diphosphate, and is identified as adenosine.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the labeled protein target taught in the method of Burmer as modified by Baek with glycoprotein or a platelet membrane receptor protein as taught by Kutsuna to screen for compounds having biological activity, i.e. platelet

aggregation inhibition, because Burmer specifically taught application of his methods for drug discovery of lead pharmacological compounds from multiple proteins and polypeptides extracted from plant or animal tissue such as C. tinctorius, as taught by Baek, and that has been identified as having compounds which are capable of platelet aggregation inhibition, affecting platelet membrane receptor glycoprotein IIb/IIIa as in the teaching of Kutsuna.

Burmer, Baek et al. and Kutsuna et al. have been discussed supra. Burmer, Baek et al. and Kutsuna et al. differ from the instant invention in failing to disclose that the recovered compound has a molecular weight of 268 gm/mole and is self-polymerizable.

It is, however, maintained that inherent properties of an isolated active compound, i.e. molecular weight of 268 gm/mole and self-polymerizability, that has been identified in this case as adenosine, can be obtained using routine optimization procedures. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover optimum values of inherent properties by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). Accordingly, it would have been obvious for one of ordinary skill to have discovered the optimum values of inherent properties of isolated active compounds obtained in the method disclosed by Burmer from plants or herbs such as C. tinctorius as taught by Baek, having biological activity as identified by Kutsuna, by normal optimization procedures.

Response to Arguments

6. Applicant's arguments filed 12/16/04 have been fully considered but they are not persuasive.

A) Applicant argues that the combination of references fail to render the claimed methods prima facie obvious because they fail to teach or suggest the use of crude plant extract fractions containing multiple protein components to screen for a polypeptide that binds a target. Applicant specifically contends that the chromatographic separation recited in the claimed invention produces individual fractions containing multiple protein components, which is different from the teaching of Burmer, which is limited to the use of nucleic acids extracted from plant tissue separated by gradient centrifugation. Applicant then argues that Burmer does not teach or suggest use of libraries of proteins found within crude plant extract fractions to screen for biologically active molecules using a labeled target and none of the subsequent cited references cure this deficiency.

Contrary to Applicant's argument, Burmer is not limited to the use of nucleic acids extracted from plant tissue but instead, provides that ligands coated unto the plastic plate matrix are preferably polypeptides, peptides, and small organic molecules, with proteins and polypeptides being the preferred embodiment (see column 7, lines 30-37).

In as far as the chromatographic separation of fractions containing multiple protein components, obviousness can only be established by combining or modifying

the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Baek is incorporated with the teaching of Burmer for the teaching of extracting and fractionating polypeptides from crude plant extracts using chromatographic separation methods to produce different multiple protein components. The polypeptide fractions obtained from C. tinctorius can be substituted for the polypeptides and proteins that are coated and arrayed on the plastic plates or microtiter dish of Burmer. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the fractions of polypeptides extracted from Carthamus tinctorius as taught by Baek into the plastic plate or microtiter dish used in the method and kit of Burmer, because Burmer specifically suggested obtaining ligands from any plant or animal tissue for use in simultaneously screening for compounds with biological activity and pharmacological utility, i.e. antithrombotic activity and Baek specifically extracted and fractionated polypeptides from C. tinctorius using chromatographic methods so as to obtain compounds for testing of pharmacological activity.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
March 14, 2005

Christopher L. Chin

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3/16/05